

press release

More efficacious dose of Wegovy® recommended by the European Medicines Agency can help people with obesity achieve an average of 20.7% weight loss

- The European Medicines Agency (EMA) has issued a positive opinion for a new Wegovy[®]
 7.2 mg dose, advancing its availability in the European Union (EU)
- In the STEP UP programme, people with obesity taking Wegovy® 7.2 mg lost an average of 20.7% body weight at 72 weeks; one in three people achieved 25% or more weight loss¹*
- The higher dose adds a new option for substantial weight loss while preserving muscle function and maintaining the established cardiovascular health benefits of Wegovy^{®2}

Bagsværd, Denmark, 12 December 2025 – Today, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion for a higher dose of Wegovy® (semaglutide 7.2 mg), bringing it a step closer to offering individuals with obesity in the EU a new Wegovy® option for even greater weight loss. The new dose of Wegovy® has demonstrated an average weight loss of 20.7% at 72 weeks, in people with obesity who do not have diabetes.¹* These substantial weight loss results complement the already established health benefits of Wegovy® in obesity-related complications, including significant reduction in the risk of cardiovascular events such as heart attack and stroke, and reduction in pain from knee osteoarthritis.²,³

The positive opinion is based on the results from the STEP UP and STEP UP T2D clinical trial programme in people with obesity with and without type 2 diabetes. ^{1,4} In people with obesity and without diabetes, one in three participants treated with Wegovy® achieved 25% or more weight loss at 72 weeks, with a safety and tolerability profile consistent with the approved Wegovy® 2.4 mg semaglutide dose. ¹ Data showed that the majority (84%) of the weight lost with Wegovy® came from fat mass loss, with tests confirming muscle function was preserved. ^{5,6}

"This positive opinion means a new Wegovy® option, delivering weight loss of 20.7%, could be available for people with obesity early in the new year, pending the European Commission's final approval. Wegovy® has proven health benefits in obesity, helping people reach their

individual weight goals while preserving muscle function and reducing the risk of major cardiovascular events," said Ludovic Helfgott, executive vice president and head of Product & Portfolio Strategy at Novo Nordisk. "For those who want greater weight loss, there could soon be additional options with Wegovy® so that even more people with obesity have the benefits that can improve their everyday lives and long-term health outcomes."

Novo Nordisk has also applied to the EMA for a single-dose device to deliver Wegovy® 7.2 mg. Additionally, semaglutide 7.2 mg is currently under review in the US, UK and several other countries. In the US, Novo Nordisk received the Commissioner's National Priority Voucher (CNPV) and submitted semaglutide 7.2 mg to the FDA in November 2025. Under the CNPV expedited programme, review is expected within 1–2 months following the FDA's acceptance of the filing.

About the STEP UP trials

Novo Nordisk has completed two trials, STEP UP and STEP UP T2D, investigating the efficacy and safety of semaglutide 7.2 mg in people with obesity with or without type 2 diabetes. The 72-week STEP UP trial was a randomised, double-blinded, parallel-group, placebo-controlled, superiority trial designed to evaluate the efficacy and safety of semaglutide 7.2 mg compared to semaglutide 2.4 mg and placebo as an adjunct to lifestyle intervention. The trial included 1,407 adults with a BMI ≥30 kg/m² without diabetes. The primary objective was to demonstrate superiority of semaglutide 7.2 mg against placebo on weight loss. Key confirmatory secondary endpoints included the number of participants achieving 10%, 15%, 20% and 25% weight loss, respectively. The 72-week STEP UP T2D trial investigated semaglutide 7.2 mg in 512 adults with obesity and type 2 diabetes, with the primary objective of demonstrating superiority of semaglutide 7.2 mg against placebo on weight loss.

About Wegovy®

Injectable semaglutide 2.4 mg is marketed under the brand name Wegovy[®]. In the EU, Wegovy[®] is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with a BMI of 30 kg/m² or greater (obesity) or adults with a BMI of 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition.⁷ In the EU, Wegovy[®] is also indicated for paediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and gender (obesity) and body weight above 60 kg. The clinical section of the label also includes data on Wegovy[®] major adverse cardiovascular events (MACE) risk reduction, improvements in HFpEF-related (heart failure with preserved ejection fraction) symptoms and physical function, as well as pain reduction related to knee osteoarthritis.⁷

^{*} Based on the trial product estimand: treatment effect if all people adhered to treatment.

About the EMA regulatory procedure

The European Medicines Agency (EMA) evaluates new medicines through a centralised procedure where companies submit a comprehensive dossier that includes data on quality, safety and efficacy. The Committee for Medicinal Products for Human Use (CHMP) conducts a scientific assessment and issues an opinion on whether the medicine's benefits outweigh its risks. Based on this opinion, the European Commission then adopts a legally binding decision to grant or refuse an EU-wide marketing authorisation, including any conditions or post-authorisation requirements.

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 78,500 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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